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April 3, 2003

Hearing Clerk
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rooms 1061
Rockville, MD 20852

Re: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (Docket No. 02N-0278)

Dear Hearing Clerk,

These comments respond to FDA's notice of proposed rulemaking published in the Federal Register February 3rd 2003, requesting public comment on a document entitled "Registration of Food Facilities Under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002". Please be advised that Chr. Hansen Inc. is a manufacturer and supplier of food products subject to the proposed regulation, namely food flavors, spices, cultures, and color additives with manufacturing and distribution facilities in New Jersey, Wisconsin, Illinois, Louisiana and Florida. In addition Chr. Hansen, Inc. has facilities in Europe that manufacture and export food products subject to this proposed rule.

Chr. Hansen, Inc. is a significant importer of food ingredients produced mainly in Denmark, but in other foreign facilities as well e.g. France, Germany and the United

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Kingdom. We appreciate this opportunity to provide our comments to FDA relating to the critical proposed rule.

We share in FDA's concern as to the need to provide the greatest security possible for all food imports. We agree with most of the requirements set forth in the proposed rule and will work with our facilities and other suppliers to assure compliance with these requirements.

The use of electronic entry of all data for food imports will greatly facilitate these activities. The only concern we have with electronic data entry is the need for a contingency plan or backup plan in case of electronic system failure. We urge the agency to consider developing a secondary electronic backup system in case of failure of the primary system. The use of a manual system in view of the time constraints placed by these regulatory requirements is not practically feasible. A manual system should be a system of last resort or at least a third tier system used only if both electronic systems fail at the same time.

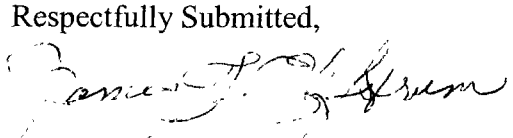
A further general concern that we have is the need for FDA to communicate with potential stakeholders as to the scope if the proposed regulations. We are aware of some communications along these lines, but further efforts are needed to communicate as to the scope of this matter, so that all importers of food gain access to the electronic database well before implementation of final rulemaking. In this respect, FDA needs to define to the affected food industry as broadly as possible in terms of this regulatory endeavor.

Another area of concern relates to section 801(a) admissibility decisions versus 802(m) prior notice admissibility decisions. We urge FDA to cooperate to the greatest extent possible to simultaneously consider 801(a) and 801 (m) issues thereby coordinating these determinations with the US. Customs Service. It serves no useful purpose to add another layer of regulatory review, if these two determinations can be combined to facilitate food security and commerce in a single step.

The proposed regulation requires the use of a FDA product code as an element of the identity of the product. Attempts to gain internet access to the FDA product database have not been successful. We urge FDA to correct the situation as soon as possible.

Chr. Hansen appreciates this opportunity to provide comment to the agency with respect to the prior notice of imported food requirements and looks forward to the publication of a final rule.

Respectfully Submitted,



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